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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/558,038

Applicant(s)

BIENHAUS ET AL.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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## DETAILED ACTION

### *Specification*

1. Claims 13, 17, 20, 21, 28, and 34 have been amended.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 13-18, 22-28, and 30-35 are rejected under 35 U.S.C. 102 (e) as being anticipated by Reeve (U.S. Patent 5,523,231) (June 4, 1996).

Reeve teaches a method of isolating nucleic acid from biological compartments of a fluid sample (Abstract) comprising the steps of:

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a) incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments (Abstract and Figures 1-2, especially step 1, and Examples 1-8);

b) positioning at least one magnet towards the sample processing vessel such that the magnet holds the magnetic particles against an inside wall of the sample processing vessel by magnetic force (Figures 1-2, especially step 4);

c) removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel (Figures 1-2, especially step 5);

d) introducing a second fluid into the sample processing vessel (Figures 1-2, especially step 6);

e) resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel (Column 4, lines 31-36);

f) lysing the biological compartments to form a lysis mixture (Claims 4-5); and

g) isolating the nucleic acids from the lysis mixture (Column 4, lines 36-44 and Claims 4-5).

Reeve teaches a method, wherein essentially all of the magnetic particles have a diameter of 2.8 micrometer to 200 micrometer (Column 2, lines 59-61 and Column 8, lines 52-53).

Reeve teaches a method, wherein the isolation step comprises immobilizing the nucleic acids on the magnetic particles (Figures 1-2).

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Reeve teaches a method, wherein the nucleic acids to be isolated are transferred to a vessel which is configured to receive a pipette (Column 4, lines 39-44).

Reeve teaches a method, wherein the magnetic force is eliminated by separating by a sufficient distance the at least one magnet from the outside wall of the sample processing vessel (Column 4, lines 33-36).

Reeve teaches a method, wherein the processing vessel containing the sample is shaken during at least a portion of the incubation step to facilitate binding (Column 4, lines 31-36).

Reeve teaches a method, wherein the magnetic force is eliminated and the sample processing vessel is shaken simultaneously (Column 4, lines 31-36 and Example 6 and Column 5, lines 36-38).

Reeve teaches a method, wherein the steps a) to g) are repeated until the biological compartments have reached a desired level of purity (Claims 4-5).

Reeve teaches a method, wherein the fluid sample is a body fluid which is blood (Example 8, especially column 11, lines 45-50).

Reeve teaches a method, wherein the nucleic acids are present and detected in the sample reaction vessel in a block throughout the removing, resuspending and lysing steps (Examples 6-8 and Claims 4-5).

Reeve teaches a method, wherein the lysis mixture is warmed to a temperature around room temperature or higher (Example 7, column 10, lines 65-67).

Reeve teaches a method, wherein the lysis mixture is cooled under conditions that make it possible to isolate or hybridize the nucleic acids to be isolated or detected (Example 5).

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 20, 21, and 29 are rejected under 35 U.S.C. 103 (a)) as being obvious over Reeve (U.S. Patent 5,523,231) (June 4, 1996).

Reeve teaches all limitations of claims 13 and 27.

Reeve does not teach the specific weight of the magnets which is in the range of 0.5 g to 5 g and warming of the lysis mixture to a temperature of about 70 degree to 95 degree centigrade.

However, it is *prima facie* obvious that the selection of the specific weight of the magnet and warming of the lysis mixture to a particular temperature represent routine optimization with regard to the sizes of the biological compartments and nucleic acid molecules to be isolated and the requirement of isolation speed which routine optimization parameters are explicitly

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recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of the specific weight of the magnet and warming of the lysis mixture to a particular temperature performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

#### ***Response to Amendment***

6. In response to amendment, 112 (second paragraph) rejections are hereby withdrawn. However, 102(e) and 103(a) rejections are properly maintained.

#### ***Response to Arguments***

7. Applicant's arguments filed on August 23, 2002 have been fully considered but they are not persuasive. Applicant argues that Reeve reference does not teach the important feature of the present invention, i.e., the shaking step. This argument is not persuasive. Reeve clearly and distinctly teaches "the shaking step" inherently (vortex mixing in this case on Column 4, lines 31-33).

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Applicant argues that Reeve reference does not teach the warming of the lysis mixture of the claimed invention. Applicant argues that the word “warming” was not found in Reeve reference. Applicant argues that because Reeve has a preferred embodiment of isolating nucleic acids at a lower temperature, Reeve is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states “Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971).” MPEP 2123 also states “A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 10 USPQ2d 1843 (Fed. Cir. 1989).” It is clear that simply because Reeve has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. For example, Reeve teaches the warming step on Example 6 (Column 10, lines 65-67). Moreover, MPEP 2111 states, “Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be “given the broadest reasonable interpretation consistent with the specification”. Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)”. In this case, any warming of the lysate under any suitable conditions can be used for nucleic acid extraction.



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In view of the response to arguments, 102(e) and 103(a) rejections are hereby properly maintained

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

September 9, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600